

## SCIENTIFIC OPINION

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## Safety of natural mixture of dolomite plus magnesite and magnesium-phyllsilicates (Fluidol) for all animal species

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### Abstract

The additive under assessment consists of a natural mixture, mainly composed of dolomite (~ 30%), magnesite (~ 20%) and magnesium-phyllsilicates (talc (~ 35%) and chlorite (~ 15%)). In 2016, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) delivered an opinion on the safety and efficacy of natural mixture of dolomite plus magnesite and magnesium-phyllsilicates. In this opinion, the Panel concluded that 20,000 mg additive/kg complete feed is considered safe for dairy cows and for piglets (weaned). This conclusion was extended to pigs for fattening while no conclusion could be drawn on the safety for poultry or any other species/categories. Following this opinion, the European Commission gave the possibility to the applicant to submit complementary information in order to complete the assessment on the safety for all animal species. The new tolerance studies submitted with cattle for fattening and chickens for fattening showed tolerance of these animal categories to the additive up to approximately fivefold the highest recommended use level. The FEEDAP Panel therefore concluded that 20,000 mg additive/kg complete feed is safe for cattle for fattening and chickens for fattening. The additive at the same dietary concentration was already considered safe in an earlier opinion for piglets and dairy cows. Since the additive at 20,000 mg/kg complete feed is considered safe for four animal categories (three major animal species) with a comparable margin of safety, the conclusion on safety is extrapolated to all animal species. At the safe dietary concentration the additive did not affect the digestibility of the feed (including feed additives).

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## 1. Introduction

### 1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003<sup>1</sup> establishes the rules governing the Community authorisation of additives for use in animal nutrition and, in particular, Article 9 defines the terms of the authorisation by the Commission.

The applicant, IMI FABI S.p.A., is seeking a Community authorisation of natural mixture of dolomite plus magnesite and magnesium-phyllsilicates (Fluidol), when used as a feed additive for all animal species (category: technological additives; functional group: anticaking agents) (Table 1).

**Table 1:** Description of the substances

<b>Category of additive</b>	Technological additives
<b>Functional group of additive</b>	Anticaking agents
<b>Description</b>	Mixture of dolomite plus magnesite and magnesium-phyllsilicates
<b>Target animal category</b>	All animal species
<b>Applicant</b>	IMI FABI S.p.A.
<b>Type of request</b>	New opinion

On 25 January 2017, the Panel on Additives and Products or Substances used in Animal Feed of the European Food Safety Authority ("Authority"), in its opinion on the safety of the product, concluded that no reason was identified to modify the conclusions reached in the previous opinion.

Following the discussion at the Standing Committee on Plants, Animals, Food and Feed, Section-Animal Nutrition, on 24 April 2017, the Commission gave the possibility to the applicant to submit complementary information in order to complete the assessment on the safety and to allow a revision of Authority's opinion.

On 1 September 2017, the Commission has received new data from the applicant.

In view of the above, the Commission asks the Authority to deliver a new opinion for the natural mixture of dolomite plus magnesite and magnesium-phyllsilicates (Fluidol), when used as a feed additive for all animal species based on the additional data submitted by the applicant.

### 1.2. Additional information

In 2016, the FEEDAP Panel delivered an opinion on the safety and efficacy of a natural mixture of dolomite plus magnesite and magnesium-phyllsilicates (Fluidol) as a feed additive for all animal species (EFSA FEEDAP Panel, 2016). In this opinion, the Panel concluded that the additive is safe for the consumer, the user and the environment. The additive was also considered effective as an anticaking agent at a minimum inclusion level of 5,000 mg/kg feed. However, regarding the safety for the target animals, the Panel concluded that the proposed supplementation level of MDMM (20,000 mg MDMM/kg complete feed) is considered safe for dairy cows and for piglets (weaned) and pigs for fattening but no conclusion could be drawn on the safety for poultry or any other species/categories.

In 2017, the FEEDAP Panel was requested to assess additional information submitted by the applicant. In its opinion (EFSA FEEDAP Panel, 2017), the Panel analysed a different interpretation given by the applicant of the results of the tolerance studies with dairy cows and chickens for fattening assessed in the previous opinion (EFSA FEEDAP Panel, 2016). In the absence of any new data, the Panel concluded that 'no reason was identified to modify the conclusions reached in the previous opinion'.

### 1.3. Interpretation of the terms of reference

In the view of the above, the current opinion will focus on the assessment of the safety of the additive for the target species.

<sup>1</sup> Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

## 2. Data and methodologies

### 2.1. Data

The present assessment is based on the data submitted by the applicant in the form of additional information<sup>2</sup> following two previous applications on the same product.<sup>3</sup>

### 2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety of natural mixture of dolomite plus magnesite and magnesium-phyllsilicates (Fluidol) is in line with the principles laid down in Regulation (EC) No 429/2008 and the relevant guidance documents: Guidance on technological additives (EFSA FEEDAP Panel, 2012) and the Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011).

## 3. Assessment

The product under assessment is a natural mixture mainly composed of dolomite (~ 30%), magnesite (~ 20%) and magnesium-phyllsilicates (talc (~ 35%) and chlorite (~ 15%)), subsequently referred to as MDM. It was described and properly characterised in a previous opinion (EFSA FEEDAP Panel, 2016).

The additive is intended to be used as a technological additive (functional group: (i) anticaking agents) in premixtures and feedingstuffs for all animal species and categories, with no minimum and maximum content. The applicant proposed use levels in premixtures and feedingstuffs of 5,000–20,000 mg/kg.

The FEEDAP Panel delivered two opinions on the additive under assessment (EFSA FEEDAP Panel, 2016, 2017). In the current application, the applicant submitted two new tolerance studies, one in cattle for fattening and one in chickens for fattening.

### 3.1. Safety for the target species

In its previous opinion (EFSA FEEDAP Panel, 2016), the Panel concluded that the additive is safe for dairy cows at a concentration of 20,000 mg/kg complete feed, however, a margin of safety could not be identified. Consequently, this conclusion could not be extrapolated to other ruminants. In the same opinion, the safety for chickens for fattening could not be shown, because the data indicated a worsening effect on feed to gain ratio in all the treated groups. In order to complete the assessment of the safety for all animal species, the applicant submitted two new tolerance studies, one in cattle for fattening and one in chickens for fattening.

#### 3.1.1. Safety for cattle for fattening

A total of 63 Holstein bulls (average age: 146 days; average body weight: 201 kg) was fed mash concentrates supplemented with 0, 20,000 (1× highest proposed use level), 50,000 (2.5×) or 100,000 (5×) mg MDM/kg and straw for 49 days. The concentrate and straw were offered *ad libitum*.<sup>4</sup> Group size was four replicates with four bulls each (except one with three bulls in the 1× group). The concentrates were isonitrogenous (about 15.8% CP) and isocaloric (about 8.5 MJ NE/kg), achieved by an increase of corn gluten feed, beet pulp and palm oil with increasing content of the additive. It is noted that the incorporation of 100,000 mg MDM/kg in an isonitrogenous and isocaloric diet involved many changes in the diet composition that makes the comparability of this diet with the three others questionable. The concentration of the additive was analytically confirmed (by analysis of iron as the marker). Individual body weight and pen feed intake (including straw consumption) were recorded at day 0, 14, 28, 42 and 49. Feed to gain ratio was calculated for the different periods. At start and end of the experiment, blood samples were obtained from the same eight animals per treatment (two pens per

<sup>2</sup> Dossier reference: FAD-2018-0001.

<sup>3</sup> Dossier reference: FAD-2012-0043 and FAD-2016-0042.

<sup>4</sup> Technical dossier/Annex 1A, Annex 1B, Annex 1C, Annex 1D Annex 1E and Annex 1F.

treatment) and analysed for haematology<sup>5</sup> and clinical chemistry.<sup>6</sup> Data on feed consumption, growth and feed efficiency were analysed using a linear mixed-effects model with repeated measurements. The model accounted for the fixed effects of treatment, time and the interaction between these two factors; pen was considered a random effect. Initial body weight was used as a covariate. Data on blood parameters of days 0 and 49 were analysed using a linear model with the fixed effects of treatment.

No mortality occurred in the trial. Mean final body weight was 290 kg without differences between the groups. No adverse effects of the additive on the intake of concentrate and total feed dry matter (DM), on the total feed DM to gain ratio were observed (control group: concentrate intake 6.16 kg/day, total DM intake 6.64 kg/day, total DM to gain ratio 3.60). No differences were seen in the haematological and clinical biochemistry parameters among the groups, with the exception of glucose (lower in the control group compared to the 1× and the 2.5×, but not the 5× groups) and total protein (higher in the control group compared to the 1× and the 5×, but not the 2.5× groups).

The results show that complementary feed for cattle for fattening containing up to 100,000 mg MDMM/kg, corresponding to approximately 93,000 mg MDMM kg complete feed<sup>7</sup> can be formulated and fed without causing adverse effects to the cattle.

### 3.1.2. Safety for chickens for fattening

A total of 600 one-day-old male chickens (Ross 308) was fed pelleted diets supplemented with 0, 20,000 (1 × the highest recommended use level), 50,000 (2.5×) or 100,000 (5×) mg MDMM/kg for 35 days.<sup>8</sup> Group size was 6 replicates with 25 birds each. The diets (starter, from day 0 to day 21; grower, from day 22 to day 35) consisting mainly of maize and soybean meal, were isonitrogenous (starter: about 21.2% CP; grower: about 19.5% CP) and isocaloric (starter: about 12.3 MJ ME/kg; grower: about 12.7 MJ/kg, by an increase of soy oil and full fat extruded soybeans with increasing content of the additive). The intended concentrations of the additive were analytically confirmed (by analysis of iron). The diets contained 100 mg monensin sodium/kg. Body weight and feed intake were recorded at days 21 and 35. Feed to gain ratio was calculated for the corresponding periods. At the end of the experiment, blood samples were taken from one chicken per pen for haematology<sup>9</sup> and clinical chemistry.<sup>10</sup> An analysis of variance (ANOVA) was done with the data considering the treatment and the block (location of the pen) in the model and using the pen as the experimental unit. Group means were compared with Duncan's multiple range tests.

Overall mortality was low (0 birds in the 1× group, 3 birds each in groups 0 and 5× and 5 animals in the 2.5× group). No differences were observed on the performance parameters among the groups (control group: final body weight 2.29 kg, average daily feed intake 94 g and feed to gain ratio 1.46).

The only haematological parameters which were affected by MDMM, but not in a dose-dependent manner, were haematocrit (higher in the 5× group compared to the 1× group) and haemoglobin (higher in the 2.5× group compared to the control group). No differences were observed in any of the clinical biochemistry parameters.

The results show that complete feed for chickens for fattening containing up to 100,000 mg MDMM/kg can be formulated and fed without causing adverse effects to chickens for fattening.

### 3.1.3. Interaction with nutrients and feed additives

A study in chickens was provided,<sup>8</sup> in which a total of 32 one-day birds was distributed to 16 cages (2 birds per cage) and fed the same starter diets as described in the tolerance study for the control group and the group receiving 20,000 mg MDMM/kg feed (representing 8 replicates per treatment).

<sup>5</sup> Haemoglobin, red blood cell count, packed cell volume, mean corpuscular volume, mean corpuscular haemoglobin, mean corpuscular haemoglobin concentration, white blood cell count, white blood cell differentials (neutrophils, lymphocytes, monocytes, eosinophils, basophils, platelets).

<sup>6</sup> Alanine transaminase, alkaline phosphatase, aspartate aminotransferase, creatine phosphokinase, gamma-glutamyl transpeptidase, glutamate dehydrogenase, glutathione peroxidase, lactate dehydrogenase, albumins, total protein, glucose, urea, calcium, iron, magnesium, potassium and sodium.

<sup>7</sup> The total dry matter feed intake in the study consisted of approximately 93 % concentrate and 7% straw.

<sup>8</sup> Technical dossier/Annex 3A, Annex 3B, Annex 3C and Annex 3D.

<sup>9</sup> Haemoglobin (Hb), red blood cell count (RBC), packed cell volume (PCV), mean corpuscular volume (MCV), mean corpuscular haemoglobin (MCH), platelets, white blood cell count (WBC), white blood cell differentials (segmented neutrophils, banded neutrophils, lymphocytes, monocytes, eosinophils).

<sup>10</sup> Alanine transaminase (ALT), alkaline phosphatase, aspartate aminotransferase (AST), creatine phosphokinase (CPK), gamma-glutamyltranspeptidase (GGT), glutamate dehydrogenase (GLDH), glutathione peroxidase (GSH-Px), lactate dehydrogenase (LDH), albumins, globulins, total protein, glucose, uric acid, phosphate.

Titanium dioxide (0.5%) was used as an inert marker for the digestibility/adsorption measurements. Excreta were collected from days 18 to 21. Nitrogen, uric acid, vitamin E (alpha-tocopherol and alpha-tocopherol acetate), riboflavin, pyridoxine, zinc and monensin (and titanium) were analysed and the digestibility/absorption calculated. The data were evaluated by a one-way ANOVA.

None of the end-points selected for assessing the potential influence of the additive on the digestibility/absorption of nutrients and feed additives (faecal nitrogen, alpha tocopherol and alpha tocopherol acetate, riboflavin, pyridoxine, zinc and monensin) indicated an effect of the additive at the concentration of 20,000 mg/kg complete feed.

#### 4. Conclusions

The tolerance studies with cattle for fattening and chickens for fattening showed tolerance of these animal species/categories to the additive MDMM up to approximately fivefold the highest recommended use level. The FEEDAP Panel therefore concludes that 20,000 mg MDMM/kg complete feed is safe for cattle for fattening and chickens for fattening. The Panel notes that MDMM at the same dietary concentration was already considered safe in an earlier opinion for piglets and dairy cows (EFSA FEEDAP Panel, 2016). Since MDMM at 20,000 mg/kg complete feed is considered safe for four animal categories and shows a comparable margin of safety in three major animal species, the conclusion on safety is extrapolated to all animal species.

At the safe dietary concentration, MDMM does not affect the digestibility of the feed components (including feed additives).

#### Documentation provided to EFSA

- 1) Natural mixture of dolomite plus magnesite and magnesium-phyllsilicates (Fluidol) for all animal species. December 2017. Submitted by IMI FABI S.p.A.

#### References

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#### Abbreviations

ANOVA	analysis of variance
CP	crude protein
DM	dry matter
FEEDAP	Panel on Additives and Products or Substances used in Animal Feed
MDMM	Natural mixture of dolomite plus magnesite and magnesium-phyllsilicates